SharpLight

K082876

510(k) Summary

NOV 10 2008

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.92

Submitter Information

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Device Classification

Proprietary Device Name:	BEAMAX/ FORMAX Pulsed Light Device Family
Common name:	Fluorescent Pulsed Light System
Produt Code:	GEX
Classification Name:	Laser Surgical Instrument, for use in General and Plastic Surgery and Dermatology
Classification Regulation:	21 CFR § 878.4810
Regulatory Class:	II

Identification of Legally Marketed Predicate Devices

Cutera Optional Pulsed Light Hand Piece Family - K050047
Alma - Harmony XL™ Multi-Application Platform – K072564
SharpLight – BEAMAX Pulse Light System - K063249

Device Description

The proposed BEAMAX/ FORMAX family system is a pulsed light energy device based on a filtered, Xenon flashlamp.
The total emission spectrum of a Xenon flashlamp is from around 300 nm in the UV to 1000 nm in the near IR. The light emitted from the lamp is collected by a reflector and focused into a rectangular, waveguide. Prior to entering the waveguide, the light is transmitted through a long-pass optical filter which blocks all wavelengths below the "cut-off" wavelength of the filter. Thus when a 635nm filter is used, only light of wavelengths above 635 nm is emitted. Since the lamp is surrounded by a water cooling jacket, actual wavelength emission is up to about 950 nm, due to water absorption of longer wavelengths.
The BEAMAX/FORMAX family system is equipped with four different handpieces which can be attached for different clinical applications. These handpieces differ in the optical filter applied, hence in the optical spectrum emitted, as well as in the time duration of the pulses emitted.
A microprocessor based system controller is used to monitor and direct all system functions and Man Machine Interface.

Intended Use of Device

The BEAMAX/ FORMAX Pulsed Light Device Family and optional Handpies family are intended for use in aesthetic and cosmetic applications and in selective treatments required in the medical specialties of dermatology.
The BEAMAX/ FORMAX Pulsed Light Device Family and optional Handpies family with 415 – 950 nm wavelengths (with and without contact-cooling) are indicated for:
* Hair removal in all skin types to the Fitzpatrick scale. Permanent Hair Reduction.
* Treatment of Vascular Lesions
* Treatment of Inflammatory Acne (acne vulgaris)
* Treatment of Benign Pigmented Epidermal and Cutaneous Lesions including warts, scars and striae.

Safety & Effectiveness

The intended use and indications of the submitted BEAMAX/ FORMAX pulsed light system family is identical to the legally marked devices: BEAMAX (K063249 - for hear removal treatments); Harmony XLTm Multi-Application Platform (K072564); Cutera Optional Pulsed Light Hand Piece Family (K050047).
Similarity of intended use and intended use and technological features and therefore the risks and benefits are comparable to the predicate devices.
We therefore believe that there are no new questions of safety or effectiveness raised by the introduction of sharpLight's BEAMAX/ FORMAX Fluorescent Pulsed Light Systems.

Rational for Substantial Equivalency

Similarities:
The intended use and indications of the proposed modified BEAMAX/ FORMAX device family are similar to the legally marketed predicate devices.
The technology, performance and most of the specifications of the proposed modified BEAMAX/ FORMAX device family are similar to the legally marketed predicate devices
Differences:
The proposed modified device family includes wider indications in reference to legally marked BEAMAX (K063249) indication for use that is limited to Hair removal only.
The proposed device family intended use and indications for use are similar to the IPL intended and indications for use of Harmony XLTm Multi-Application Platform (K72564) and Cutera Optional Pulsed Light Hand Piece Family (K050047) predicate devices (Other indications are related to optional Laser handpieces).

Substantial Equivalence Statement

Based on the above, it is SharpLight's opinion that the proposed BEAMAX and FORMAX Pulsed Light Device Family is substantially equivalent in terms of design, functional features and safety & effectiveness to the unmodified BEAMAX (K63249) legally marketed device and to the legally marked predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 2008

SharpLight Technologies, Ltd.
% Ilan Sharon
11 Moshe Levy St
Rishon Le Zion 75658, Israel

Re: K082876
Trade/Device Name: BEAMAX/FORMAX Pulsed Light Device Family
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: October 15, 2008
Received: October 21, 2008

Dear Ilan Sharon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082876

Device Name: BEAMAX/ FORMAX Pulsed Light Device Family

Indications for Use:

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The BEAMAX/ FORMAX Pulsed Light Device Family and optional Handpies family with 415 – 950 nm wavelengths (with and without contact-cooling) are indicated for:

* Hair removal in all skin types (I-VI) to the Fitzpatrick scale. Permanent Hair Reduction.
  - Recommended wavelengths in the range of 635-950 nm or 580-950 nm
* Treatment of Vascular Lesions in all skin types (I-VI) to the Fitzpatrick scale – Recommended wavelength in the range of 535-950 nm
* Treatment of Inflammatory Acne (acne vulgaris) in skin types (I-V) to the Fitzpatrick scale – Recommended wavelength in the range of 535-950 nm
* Treatment of Benign Pigmented Epidermal and Cutaneous Lesions including warts, scars and striae in all skin types (I-VI) to the Fitzpatrick scale - Recommended wavelength in the range of 415-950 nm

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082876